K040144

APR - 1 2004 **510(k) SUMMARY**

DENTSPLY

NAME & ADDRESS:

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CONTACT: P. Jeffery Lehn

DATE PREPARED: January 21, 2004

TRADE OR PROPRIETARY NAME: QUIXX™ POSTERIOR RESTORATIVE

CLASSIFICATION NAME: Tooth shade resin material (872.3690

PREDICATE DEVICES:

Dyract® AP Restorative	K973235
SureFil™ Posterior Restorative	K973221

DEVICE DESCRIPTION: QUIXX™ POSTERIOR RESTORATIVE is a hybrid resin-composite restorative material for use in filling posterior dental cavities. The restorative consists of a single paste that is visible light cured.

INTENDED USE: QUIXX™ POSTERIOR RESTORATIVE is indicated for posterior Class I and II cavities.

TECHNOLOGICAL CHARACTERISTICS: All of the components of QUIXX™ POSTERIOR RESTORATIVE are found in the legally marketed predicate devices. K973221 and K973235.

QUIXX™ POSTERIOR RESTORATIVE was tested for cytotoxicity and mutagenicity and found to be non-cytotoxic and non-mutagenic.

The prior use of all of the components in legally marketed predicate devices support our decision that additional biocompatibility studies with the final formulation are not necessary.

We believe that the prior use of the components of QUIXX™ POSTERIOR RESTORATIVE in legally marketed devices, and the performance data and results of biocompatibility testing provided, support the safety and effectiveness of QUIXX™ POSTERIOR RESTORATIVE for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Dentsply International
Mr. P. Jeffery Lehn
Director of Corporate Compliance & Regulatory Affairs
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17405-0872

Re: K040144
Trade/Device Name: QUIXX™ Posterior Restorative
Regulation Number: 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: January 21, 2004
Received: January 22, 2004

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K040144

Device Name: QUIXX™ POSTERIOR RESTORATIVE

Indications for Use:

Indicated for posterior Class I and II cavities.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040144

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)